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INVENTOR(S)

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TITLE OF THE INVENTION (280 characters max)

Test method for predicting wear of polymeric devices and materials

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ENCLOSED APPLICATION PARTS *(check all that apply)*

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Date 2 June 04

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Predictive Test Methods for Wear of a Polymer on Bone Orthopedic Device

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Abstract

Two test methods, used to estimate wear of a polyurethane device bearing on osteoarthritic bone, have been developed which can be used to estimate the wear of the orthopedic implant on a knee simulator: a tensile test and a short term wear test. For the tensile test, a multiple regression produced the equation: wear = 364/e +13986/y-85381/(ys) in which y = modulus at yield , e = elongation , and s = % strain at yield. The short term wear test is conducted on a commercial specimen polisher and incorporates many of the conditions of the wear test of the knee simulator including a rough, lubricated surface, and cyclic motion which generate frictional wear. It was found that to obtain useful information, the knee simulation and wear test must use similar conditions. Under conditions which fracture and not fatigue predominate, it was found that temperature, roughness, load, and processing conditions altered wear while velocity of the wear surface did not. Results from both the tensile and short term wear test are well correlated to wear within 10% SD of the measured values from a knee simulation test.

Introduction

A permanent polymeric orthopedic implant has been developed at Advanced BioSurfaces (ABS) in which the appositional faces are osteoarthritic bone of the medial compartment of the knee. It is essential to develop test methods which can be reliably used to help predict the wear behavior of this device under the demanding conditions that the knee imposes. Numerous researchers have attempted to develop methods which predict wear of orthopedic devices during physiologic conditions. A comprehensive review by Clark list some of the early studies (1) . Most studies are concerned with the wear of polyethylene against smooth metal surfaces used in the typical total knee or hip replacement devices. Relatively few studies have aimed at the wear of materials against bone. This paper describes a tensile test and a wear test which produce results that mimic a full scale knee simulation in which the implanted device is placed against osteoarthritic bone. The materials of interest are primarily polyurethanes but the testing appears applicable to other polymers.

Previous researches have demonstrated aspects of various types of wear testing which shed much light on this case. One of the more general and applicable concepts is that of a critical point as describe by Cho and others (2). Wear is found to proceed primarily by fatigue below this point and above which wear is dependent on abrasion or perhaps a combination of abrasion and fatigue. In Cho's work, the critical point was found to be a function of the crosslink density and corresponded to the fracture energy of the polymer. Thavanani, Steijn, and Gent(3, 4, 5) have describe a critical point in terms of load and the appearance of Schallamach waves. Persson (13) describes a similar phenomenon in terms of whether or not a polymer responds in an elastic or plastic mode which is related to crosslinking and temperature.

Several other factors greatly influence wear during practical testing. The effect of temperature is extremely important if not obvious in this type of wear testing. Furukawa , Grosch and Ahagon (6,7,8) and others have demonstrated that small changes in temperature, on the order of 5 degrees can significantly alter wear rates in disproportion to the temperature rise. Ahlroos and Saiko (9,10) have extensively studied wear and pointed to the effects of the type of lubrication, whether or not the wear directions is one or two dimensional, and if motion is cyclic or not as important considerations.

The knee wear simulator used in conjunction with this work is denoted as the Knee Motion Machine (KMM) to distinguish it from knee simulators which use muscle simulation (14). The KMM was developed at ABS and has been used as the best means to simulate actual physiological conditions in the knee and to identify products of wear. It is a position controlled machine. Motions for flexion, anterior /posterior displacement and load profile are described by Chassin (15) for unicompartmental loading with a maximum load of 1600 N. The KMM has become an integral and essential part of the qualification of the of our orthopedic device. Wear results of devices tested on the KMM compare favorably with explanted devices in terms of retrieved particle size and particulates on implant surfaces, surface morphology, wear areas and location, and the presence and spacing of Schallamach waves. However, KMM testing is an expensive and time consuming process and primarily for this reason faster and less costly screening methods were sought.

Wear Testing

The mechanisms of wear are sufficiently complex in general and particularly so in this bone on polymer system that incorporating approximate in-use conditions into the test protocol narrows the range of sources of discrepancies making it easier to obtain useful predictive information from shorter duration testing. For instance, in contrast to most wear testing for orthopedic devices, testing in this instance requires a relatively rough surface. The surface of arthritic bone is composed of not only area of partial coverage cartilage but also of eburnated or bare roughened bone which is perforated with pores 20 to 200 micrometers in diameter(Figure 1 left).

The wear method we use for KMM screening is largely based on certain aspects of KMM testing: a reciprocating motion, relative velocities of 6 to 8 cm/sec (the femoral condyle transverses 3 to 4 cm in 500 msec. over the top of the polymer), a lubricated system, limited third body wear, loads between 2 to 5 MPa, controlled temperature, and , as mentioned above, a relatively rough surface compared to most orthopedic wear testing (70 microns vs .1 to 2 microns) . The apparatus used is a Buehler Ecomet polisher (referred to in this paper simply as "the Buehler" or "the Buehler method"). The Buehler uses a 12 in dia lower CCW rotating 12 in dia platen with an abrasive surface and an opposing CCW rotating 7 in dia sample holder. The platen was covered with a diamond impregnated plate (Buehler 15-6270) with a nominal particle size of 70 micrometers. Other coarseness levels may be used. In actuality, the surface is composed of islands 1 mm dia of the diamond particles spaced approximately 0.2 mm apart (Fig

1 right). The space between islands of abrasive decrease particulate loading on the bearing surface during the test and mimics the smoother areas of bone. The sample holder is allowed to pivot freely to equally load the three specimens. The sample holder is loaded to 66N normal to the platen and is placed tangent to the platen within 2 to 3 mm of the edge. It was found during test development that in using silicon carbide rather than a diamond plate wear rates decrease during the test and it is not recommended.

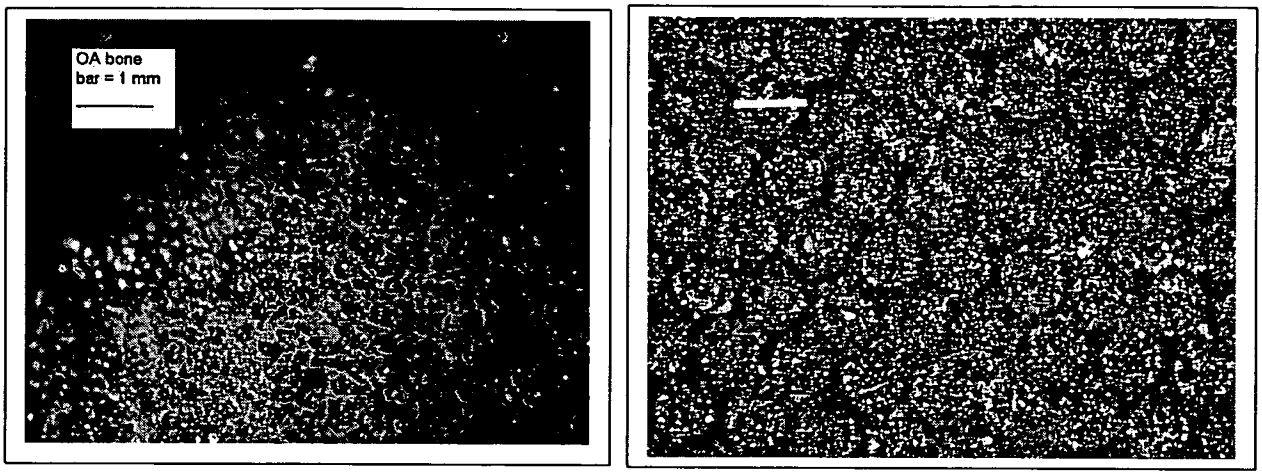
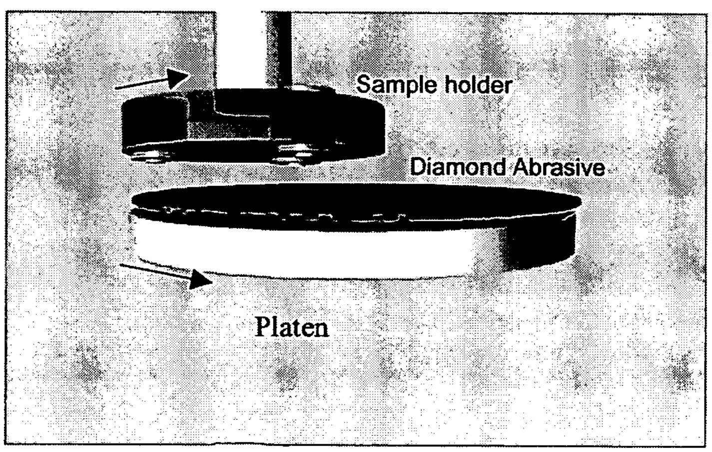


Fig 1. Optical micrographs comparing f a typical surface of the eburnated bone of a femoral condyle (left) and the abrasive surface used during Buehler testing (right) . The islands of 70 micron diamond are 1 mm dia. (bar). Many of the pores on the bone approach 1 mm but the average size is close to 0.2 mm



Left: schematic of the Buehler test setup. Three specimens are held in the sample holder inserted in polyurethane cups. The diamond abrasive sheet is comprised of a polymer backing with an adhesive.

Water from a 20 L container is circulated by a submersible pump at a rate of 500 ml/min onto the surface of the platen and back to the container through a 2 micron fibrous filter. The duration of the test is one hour. During this time no noticeable change occurs in the cloudiness of the water but the filter becomes loaded with particles. Temperature is controlled 30 C $\pm$ 1 C using an auto tuning solid state controller (Watlow 935A) and a submersible heater (Visi-Therm model VTN 100) . The mass and large surface area of the platen, large water volume and flow help maintain a constant temperature.

For each Buehler test, three specimens, between 7 mm and 12 mm thick, were cut from sheets or molded parts to a diameter of 16 mm using an ASTM D 5963 abrasion specimen cutter. For assessment and quantification of wear, wach specimen was separately weighed before and after each test and the total weight averaged at the end of the run. Individual specimen weighing gives an indication if adverse conditions arose during the test procedure as does the live time recording from the position sensor.

The specimens were held in place in the sample holder using three custom fabricated polyurethane adapters. Each adapter had a depression 3 mm deep and 16 mm dia. and was fitted with a circular disk of 240 grit adhesive backed SC paper (Buehler part 30-5112-320-psa) which prevents the specimen from spinning in the depression. The specimens were pressed into the polyurethane specimen holders with modest pressure. The Beuhler polisher was programmed to run at 80 rpm CCW for the platen, 60 rpm CCW for the sample holder, 15 lbs and 60 min. producing a nominal stress of 0.1 MPa. The vertical position of the sample holder is monitored using a linear position sensor with a sensitivity of > .01 mm. (Omega part #234234) operated at 5v from the computer. Data collection is through a WinDaq A/D converter and XL plug-in (DataQ Instruments, Springsdale, OH) for Excel software (Microsoft).

Tensile Testing

Specimens were cut from sliced cross sections of finished device or from sheet stock to 2 to 3 mm width using a dogbone die with a 2 mm center width and length of 25 mm. The prepared specimens were pulled at a crosshead speed of 25 cm /min with a MTS Bionix 400 was tensile machine. A minimum of six specimens were pulled for each material and data was automatically recorded.

NCSS (NCSS, Inc Kaysville, Utah) statistical software was used for regression analysis of the tensile data. Prism statistical graphing software (GraphPad, Inc) was used for linear regression presentation. The regression analysis included the following components: Ultimate tensile strength (UTS) , % elongation, Young's modulus , modulus at yield, strain at yield . Of these parameters, % elongation, % strain at yield, and modulus at yield were found to correlate with wear. UTS, stress at failure, peak stress, Youngs's modulus did not enter the calculations. Standard deviation for tensile results were generally less than 7 % and rarely over 10 %

Wear was estimated using: a) % elongation recorded as a fraction , b) % strain at yield, and c) modulus at yield. Equation 1 was developed from a multiple regression with forward hierarchical switching of order three and a maximum of three terms.

$$W = 364/e + 13986/y - 85381/(y \cdot s) \qquad \textit{equation 1}$$

Where

y = modulus at yield in MPa,
e = elongation as a decimal, and
s = % strain at yield.

Materials

Several types of materials were tested and used for comparative analysis. Gamma crosslinked UHMWPE supplied by DePuy, Thermedics (Wilmington MA) Carbothane 72 D and 55D and Dow Pellethane 2363 80AE and 72 D were supplied by the manufacturers. Materials designated as PU80A, PU72D and PU 55D were commercially available carbon black filled polyurethanes.

A PVC material (Wimdos corp, St Could MN formulation 1012G) was also used.. The materials used to generate the regression coefficients are listed in Table 1.

A series of polyurethanes formulated in-house were analyzed as well and. are listed in table 1 as PUF8 or PUF1 are methylenediphenyldiisocyante (MDI), polytetramethylene oxide (PTMO), and 1,4 hydroxyterminated butyleneoxide (BDO) based polyurethanes with a composition similar to that of Pellethane 55D except that 3% trimethylolpropane (TMP) was added as a crosslinking reagent. These were injectoncast as a two part system into heated metal molds. These materials contained 58 wt% hard segment and have elongations near 350%. The difference between PUF1 and PUF8 materials is the temperature of the casting process. Molding temperature caused measurable changes in the mechanical and wear properties. PUF4 and PUF6 were also manufactured in-house. These are softer materials than the PUF1 and PUF8 polyurethanes. PUF4 and PUF6 contain 45 wt% and 22 wt% percent hard segment and have elongations of 280% and 600% respectively. All in-house produced materials were annealed for a minimum of 24 hours at 120° C and used after at least six days post manufacture. Manufacture and testing was performed over a four month period.

Results

Table 1 lists the materials wear tested and used in the regression analysis along with the estimated results from the tensile testing. Table 2 list those wear tested and whose wear was estimated solely using equation 1. A linear regression of the predicted wear vs actual wear is shown in *Fig 2*. The correlation between the actual versus the estimated wear is generally quite good with differences often being less than 10%.

Materials Used to create Regressive model						
	Actual wear Ave ±10%SD mg	**Estimated wear from Regression mg**	**% Difference**	**Tensile elongation @ break/100 fraction**	**% Strain @ Yield**	**Modulus @ yield MPa**
UHMWPE xlinked GVF	60-65	62.87	0.2	1.3	1.4	216
Pellethane 80A	210	238.36	13.5	5.8	24.9	54
Carbothane 72d	156	189.48	21.5	1.49	2	81.5
Carbothane 55d	197	196.36	0.3	1.83	8.3	216
Pellethane 55d	189	168.75	10.7	2.58	12.6	152
PUF4	410	420.06	2.5	2.83	22.6	32.8
PVC	1000	959.50	4.1	1.85	50.2	15.7

Table 1 Materials and tensile parameters and result .The wear values are for 20 min of testing corresponding to a KMM test of 300,000 cycles. These materials were used to generate the regression coefficients. Values for estimated wear are from equation 1.Statistical data for the multiple regression: hierarchical with switching 3rd order,R2= .9877, Coef variation = .1610, mean sq error= 1759

Estimated Wear for Materials via Equation 1. These materials were not used in determination of the regression coefficients						
	Actual wear for 20 min of Buehler testing mg	**Estimated wear mg**	**% Difference**	**Tensile elongation @ break/100**	**%Strain @ Yield**	**Modulus @ yield MPa**
PUF1	130	149.30	14.8	2.9	8.6	136
PUF6 lot 1	110/ 600*	746.81	24.5	4.97	34.5	16.6
PUF6 lot 2	122 / 700*	621.48	11.2	6	36	20
PUF9-5 lot 1	145	163.01	12.4	3.6	15.8	105
PUF8-5 lot 1	159	147.56	7.2	3.6	14	119
PUF8-5 lot 2	152	149.98	1.3	3.97	14.3	102.58
PUF8-5 lot 3	100	113.15	13.2	3.46	9	162
PUF8-lot 1	181	158.57	12.4	3.05	12	116.4
PUF8-lot 2	153	176.68	15.5	4.29	18.5	83.9
PUF8-lot 3	135	126.37	6.4	3.35	10.8	162
PUF8-lot 4	100	113.15	13.2	3.46	9	162
PU 80A	429	411.66	4.0	6.72	12.5	18.96
PU 90A	178	200.79	12.8	2.7	11.7	78
PU 75D	420	385.49	8.2	0.9	6.2	564.7

*Table2: Materials and parameters used to estimate wear and Buehler results. The materials listed as F8 or F1 are MDI, PTMO, BDO based polyurethanes with a composition similar to that of Pellethane 55D except that 3% TMP was added as a crosslinking reagent. Differences in the materials were due to the temperature of the casting process.PUF6 was a softer polyurethane and * indicates a discrepancy in wear values which is explained in the text. The last three materials were commercially available polyurethanes. Equation 1 was used to estimate wear from the tensile data.*

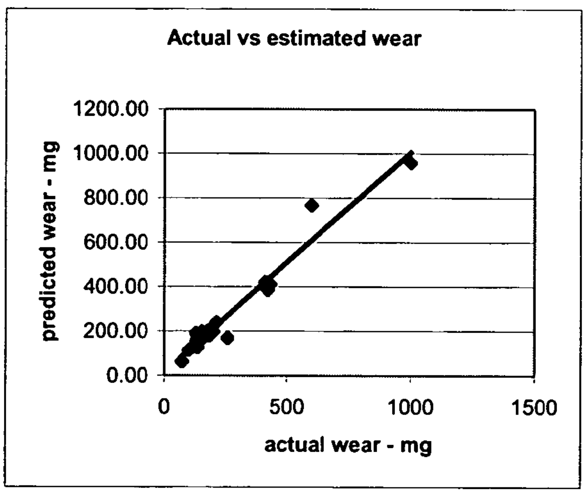
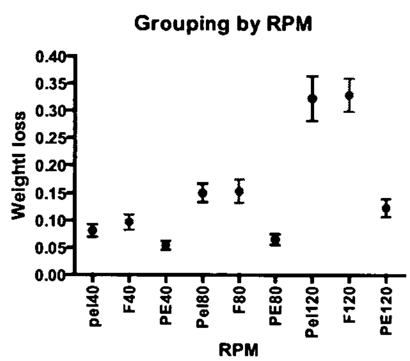


Fig 2 Plot of chart predicted wear vs actual wear from the Buehler test method. Wear testing of UHMWPE on the KMM using the implant model produces a wear of approximately 64 mg for 300,000 cycles. The parameters for the Buehler were adjusted so that this value was obtained in 20 min of testing. The complete test was 60 min in duration. Slope:0.9891 ± 0.05215, Goodness of Fit: r^2=0.9523

During test development, specimens were removed periodically to reweigh to determine mass loss over a one hour period. Because realignment of the specimens was difficult and time consuming., the position sensor was added to provide a method to continuously examine wear progress. Wear rate was then determined from a plot of the total weight loss of the specimen to the total motion of the sensor. The rate of mass loss was determined from the slope between five and 50 minutes of the sixty minutes test. the test conditions were adjusted so that mass loss from UHMWPE was 64 mg. Deviation from linearity in this time frame was less than 0.2%. For comparison to KMM data, the rate of mass loss from Buehler testing was multiplied by 20 min. corresponding to the mass loss of this material during 300,000 cycles of KMM testing.

To investigate the effect of speed and roughness of the abrasive surface, several tests were conducted with three materials under slightly different conditions. UHMWPE, Pellethane 80A, and PUF1 were run using 400 and 600 grit paper and, 20 lbs load, 20 min test run time and 40, 80 and 120 rpm for the platen (figure 3). While the increased speed did show, as expected, an increase in wear for a 20 mine run time, the rate did not increase when normalized to distance (total revolutions). In fact for the polyurethanes and UHMWPE, normalized wear decreased for 80 rpm and then increased slightly for 120 rpm. (Table 3).



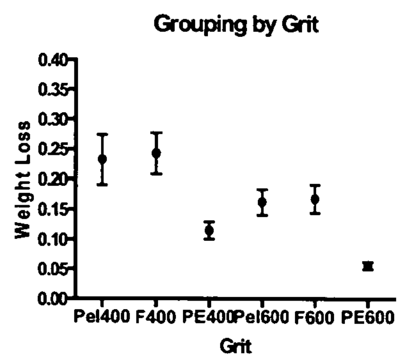


Fig 3. Left: Wear rate as function of rotational speed of the platen, and left as function of abrasiveness.(left 600 grit SC paper.) PE120 = UHMWPE @120 rpm, Pel 80= Pellethane 80A@ 80rpm, etc. Right: Same materials tested as a function of surface roughnes using 400grit and 600 grit silicon carbide paper.. For both tests, 20 min, 20 lbs, 80 rpm platen speed, n>12 Wear was proportional to surface roughness, but not to speed when equal distance was accounted for.

Material -rpm	Pel-40	PUF1-40	UHMWPE-40	Pel-80	PUF1-80	UHMWPE-80	Pel-120	PUF1-120	UHMWPE-120
mg loss RPM Normalized	80	96	54	75	75	33	106	106	40

Table 3 Mass loss normalized to 40 rpm for three materials under. For PUF1 there is a 7 % decrease in mass loss at 80 rpm and a 20% increase when the rotational speed is tripled. Normalized UHMWPE mass loss also decreases for both higher speeds.

KMM, Buehler and Tensile results.
Several materials were tested using all three methods. Some of the results are shown in table 4 normalized for 20 min. of Buehler testing (300,000 cycles of KMM testing). Buehler conditions were adjusted to match the KMM wear and it was also used in the regression analysis. UHMWPE was therefore used essentially as a control for all three methods. PUF4 was used in generating the regression coefficients so it would be expected to correlate in the comparison of Beuhler testing vs. tensile data, but the KMM wear value for PUF4 also correlates well. The various types of PUF1 were not used to generate equation 1 and the correlation here is also good.

material	KMM testing mg	Buehler testing 20 min mg	Tensile Results mg
UHMWPE	64	64	62
PUF4	400	410	420
PUF8	134	108	154
PUF1	120	130	135

Table 4. Comparison of KMM, Buehler and tensile results for three materials. Results for PUF1 have a range because of slightly different conditions of preparation and casting. PUF4 has a lower hard segment content. Each of the values represents averages from at least 10 specimens with for the KMM ~20%, and under 10% for tensile and Buehler testing

Discussion
We as others (11,12,13) have tried to correlate wear with many well known methods including several standard abrasion tests, and with standard tensile parameters as Young's modulus, hardness, elongation, peak stress, yield stress, stress at failure. Mardel (11) shows no correlation with tensile strength or fracture toughness and weak inverse correlations with hardness and elongation. Based on the testing performed, none of these parameters except elongation has led to a useful predictive data. DIN abrasion test (ASTM D 5963) or variations of pin on disc (ASTM F732-82) did not lead to useful predictive results. DIN abrasion appears to be too coarse a test with no lubrication or cyclic motion simply cutting through materials. Differential specimen heating has to be a factor in this wear test. Pin on disk is closer to our test method and should have provided equivalent information, but under standard test conditions did not do so.

The parameters which were used from tensile testing fell out of the regression analysis, but the inclusion of the parameters to use in the regression in the first place was based on the knowledge that elongation, durometer or high modulus alone are not good predictors of wear. Other factors must play a role and that these factors are knowable from material properties. Increasing modulus improves wear performance to a point. It was assumed that how long a modulus could be maintained under stress before yielding may be significant. High modulus for extended strain does appear to be an indicator based on the multiple regression. Not unanticipated, elongation to failure also appeared as a significant parameter. It seems that once yield has occurred , the better the chance for recovery leads to better wear behavior. Additionally, because improved wear behavior is inversely proportional to the three factors, the regression was conducted with the inverse values. The regression is better than when the obverse values are used. To this extent, the analysis is similar to that of Ratner (1, 2) in which wear is found to be inversely proportional to stress at failure and elongation at break. One of these terms was individually included in the regression in this work.

It appears that modulus and strain at yield are significant indicators of wear. This is exemplified in figure 4 in which wear on the vertical axis is plotted against 1/elongation and either 1/modulus at yield (left) or 1/yield strain (right). While wear is shown to be generally inversely proportional to modulus and elongation, unexpectedly, the surfaces of the plots are continuous but not smooth having peaks and valleys. This was initially thought to be due to gaps in the data from the materials selected for testing.

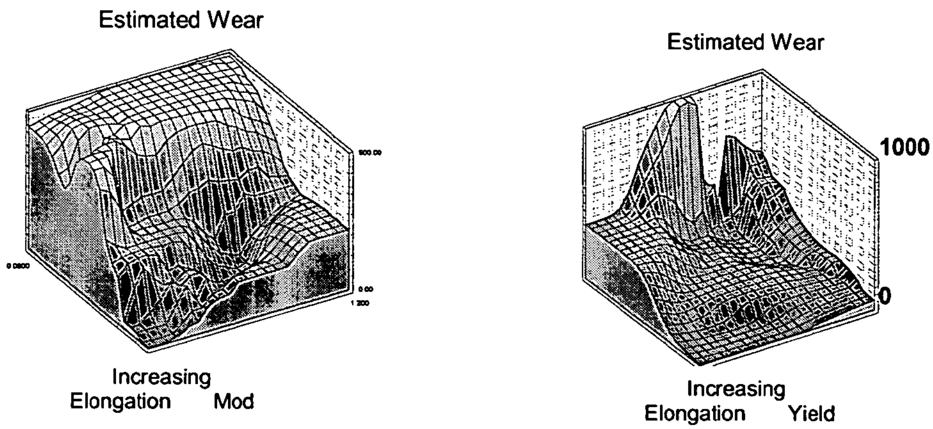
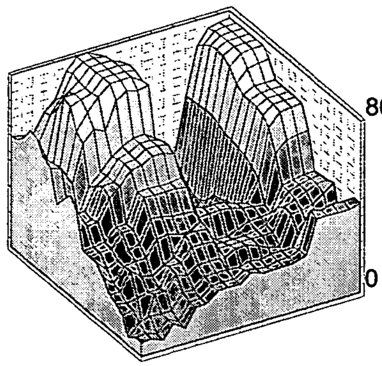


Fig 4: left: Surface plot of wear as a function of inverse elongation and modulus at yield left using constructed from the data in table 2 (strain at yield value between 2 and 20%.), and, right, as a function of inverse elongation and strain at yield (modulus at yield between 100 and 200 MPa.)

To investigate the non- uniform curvature, a plot of 600 hypothetical sets of elongation, strain and modulus between 100 to 400%, 5 to 10 %, and 100 to 200 MPa was constructed and is shown in figure 5. The plot did not become smoother, it became more convoluted. This plot shows a discreet valley as a function of 1/ yield modulus near for all lower elongations. In the valley, wear decreases for lower elongation. The model appears to indicate that at low elongation, there are combinations of yield strain and modulus that produce low wear. At high elongation, the higher the modulus, the higher the resistance to wear. At higher elongations, the effect of modulus is more continuous and modulus and elongation contribute to good wear. We have not collected sufficient data to show that this variation in wear actually occurs. Nor do we know if such materials can even be fabricated.

Estimated Wear



Increasing
Elongation and Yield

Fig. 5: Theoretical wear from 600 data hypothetical data sets(values of y,e,s) for equation 1. Two of the three parameters are use for the plot: inverse elongation and inverse modulus at yield. Strain @ yield between 5 and 10 %, modulus at yield between 100 and 200 MPa and elongation between 100% and 400 percent.

However, The regression seems to predict trends in wear reasonably well for a variety of materials so there is no particular reason to reject this result out of hand, but critical questioning may be appropriate. It would appear promising to track the behavior of materials that have tensile values producing these low wear values. Part of the intent of using commercially available materials was to cover a wide a range of values as possible, and with the exception of operating outside of the abrasive regime, equation 1 serves its purpose well. At this point, however, the complicated surface features remains a conjecture. Again it should be emphasized that such behavior, if it is real, is probably effected by the specific conditions of the testing as lubrication and specimen temperature. Persson and Tosatti (13) in their analysis of rubbers use a similar explanation to describe three different regimes of wear through a description of the frequency of contact and the loss function which describes the ability of the polymer to respond elastically or with a dissipative loss.

When different data sets are used, either incorporating more materials, or a different range of materials, different equations may be generated. For the most part the same three parameters are selected but the number of terms and order may be different. Equation 1 was generated early in the research process and has been found to be the simplest form yielding results with low SD and good consistency. It is probably more important to note that the UTS, modulus and strain at yield are selected as material properties to use in the equation rather than the specific regression equation which uses them.

The Buehler polisher provided a convenient apparatus to wear test materials. It can provide information regarding relative wear in a short time comparable to KMM simulations taking one month. It was initially investigated as a device to produce particles of specific size, and indeed can be nicely used for this purpose. But because more standard testing did not provide a correlation with KMM results, it was selected as an alternative screening method because it could more easily incorporate test conditions which were similar to the KMM. The conditions of relative velocity, stress, and surface roughness are reasonably close to KMM conditions and can

be easily altered. The method has many similarities to the method described by Saikko (10) in which he uses wear factors to describe mass loss. Wear factors were not calculated here because of the difficulty in determining the distance the specimens actually travel and the actual load on the specimens.

We are reasonably confident that third body wear is not a playing a major role in the wear process in the Buehler testing. We do know that particles are trapped in between the island of diamond abrasive, but few are seen on the surface of the islands after a test. The large volume of lubricating water also reduces this risk. Additionally, even after repeated runs of several hours with the same lubricant, the wear of UHMWPE remains constant as long as the platen is cleaned after each run.

Wear was not found to be proportional to velocity for three materials when normalized to distance (revolutions) and in fact, were found to decrease slightly. The reasons for decrease are not understood at present. Melting of the polymer probably did not occur because of the lubrication. It may be more a function of the relative position or direction of the sample holder on the platen rather a velocity issue or how well water was dragged between the specimen and platen. Wear was found to be strongly correlated to roughness of the surface as the abrasive surface was increased from 600 to 400 grit (15 to 22 micron), the material loss increased from 150 to 240 mg. However, we do know that increasing the frequency of the KMM flexion cycle from 1.2 hz to .8 can have enormous effects. The difference lies in the temperature difference that the KMM can generate on the surface of the polymer at high loads particularly after heel strike. As an indirect indication, we have seen that bovine serum, which is often used for lubrication, is for all practical purposes cooked during knee wear simulations. Thermocouples placed within test specimens also show increase in temperature. We also know that an increase in temperature of 10 deg C in the Buehler testing, by heating the lubricating solution, can result in increased wear rates.

The regression coefficients are based on the wear obtained from the Buehler measurements using specific speeds and loading. If such conditions as lubricant type and particularly temperature are altered the coefficients would be expected to change. The conditions used here are suitable when materials are subjected to wear testing that places the material in an abrasive regime. If the material is placed under milder conditions, the predicted wear will be much higher than that produced by the Buehler testing using this set of coefficients. This occurred for the material denoted as PUF6, a softer material with an elongation of over 600%. However, if PUF6 is subjected to forces which bring it into the frictional range – doubling the force for example- rather than the wear rate increase in proportion to the applied pressure as Pellethane 55D does, the wear increases by a factor greater than 5 placing the Buehler wear results close in line with the results predicted by the tensile testing. It is not known that if the tensile parameters were based on fatigue rather than abrasion if the results would have been as good.

We investigated fracture toughness as a potential predictor but to a much lesser extent. However, it does appear that some fracture parameters can be used to produce an even better correlation to wear. Specifically, the stress at yield for materials is significant as a predictor and is largely, and very importantly, independent of the slit width used in the fracture test. It would be very interesting to combine fracture and tensile values at yield to provide indicators for wear. Conversely, fracture toughness (stress extrapolated to zero slit length) is highly dependent on geometry and we found as Mardel (11) that fracture toughness did not provide useful predictive information.

Predictive estimation of wear with a precision of 10% is asking much from any test. However, slightly different processing conditions produced measurable changes in Buehler testing results tensile properties. These differences became apparent for all three methods of evaluation. Based on the work of others and this work, it appears that wear can be estimated within this range using both the Buehler and tensile testing methods, but one has to be very specific regarding the conditions of testing. The particular parameters of loading, lubrication, abrasive roughness, and particularly specimen heating effect the ability of a polymer to initially withstand an assault – overcome by modulus and yield - and then to recover through sufficient elongation. It appears that a balance of modulus and elongation provide properties for reducing wear in a particular circumstance.

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What is Claimed:

1. A tensile test method which is used to predict material properties
2. A tensile test method of claim 1 which uses standard "dogbone" specimens or which uses fracture toughness specimens in the form of rectangular sheets
3. A tensile test of claim 1 which is used to predict material properties related to the wear of materials
4. A wear test which predicts wear.
5. A wear test of claim 4 which is based on knee simulations tests.
6. A wear test of claim 4 which is used for orthopedic devices
7. A wear test of claim 4 which uses lubrication, cyclic motion, and surface roughness above about 2 micron rms as an abrasive.
8. The combination of a wear test of claim 5 and a tensile test of claim 1 to predict the wear of polymeric medical devices.